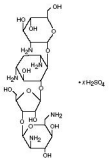
PAROMOMYCIN SULFATE - paromomycin sulfate capsule
CARACO PHARMACEUTICAL LABORATORIES, LTD.

DESCRIPTION

Paromomycin sulfate is a broad spectrum antibiotic produced by *Streptomyces riomosus* var. *paromomycinus*. It is a white, amorphous, stable, water-soluble product. Paromomycin sulfate is designated chemically as *O*-2,6-Diamino-2,6-dideoxy-β-L-idopyranosyl-(1#3)-*O*-β-D-ribofuranosyl(1#5)-*O*-[2-amino-2-deoxy-α-D-glucopyranosyl-(1#4)]-2-deoxystreptamine sulfate (salt). The molecular formula is $C_{23}H_{45}N_5O_{14}$• xH_2SO_4, with a molecular weight of 615.64 (base). Its structural formula is:



Each capsule, for oral administration, contains paromomycin sulfate equivalent to 250 mg paromomycin. Each capsule also contains the following inactive ingredients: FD&C Green #3; FD&C Yellow #5 (tartrazine); gelatin, NF; and titanium dioxide, USP.

CLINICAL PHARMACOLOGY

The *in vitro* and *in vivo* antibacterial action of paromomycin closely parallels that of neomycin. It is poorly absorbed after oral administration, with almost 100% of the drug recoverable in the stool.

INDICATIONS AND USAGE

Paromomycin sulfate is indicated for intestinal amebiasis—acute and chronic (NOTE—It is not effective in extraintestinal amebiasis); management of hepatic coma—as adjunctive therapy.

CONTRAINDICATIONS

Paromomycin sulfate is contraindicated in individuals with a history of previous hypersensitivity reactions to it. It is also contraindicated in intestinal obstruction.

PRECAUTIONS

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient is essential. If new infections caused by nonsusceptible organisms appear during therapy, appropriate measures should be taken.

The drug should be used with caution in individuals with ulcerative lesions of the bowel to avoid renal toxicity through inadvertent absorption.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

Nausea, abdominal cramps, and diarrhea have been reported in patients on doses over 3 g daily.

DOSAGE AND ADMINISTRATION

Intestinal amebiasis: Adults and Children: Usual dose—25 to 35 mg/kg body weight daily, administered in three doses with meals, for five to ten days.

Management of hepatic coma: Adults: Usual dose—4 g daily in divided doses, given at regular intervals for five to six days.

HOW SUPPLIED

Paromomycin Sulfate Capsules, each contain paromomycin sulfate equivalent to 250 mg paromomycin. The capsule is green/yellow, imprinted “175” in black ink on the cap and body.

NDC 57664-175-08: Bottles of 100

Store at controlled room temperature15°-30°C (59°-86°F).

Protect from moisture.

Caution—Federal law prohibits dispensing without prescription.

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